

## **REMARKS**

### **I. Status of the Application**

Claims 1-17 are presently pending in the application. Claims 1-9, 11, 13-15 and 17 remain rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO 91/01126. Claims 10, 12 and 16 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support for the amendment to claims 1, 2, 9 and 10 to recite "an implant that is flexible and rigid prior to insertion into an organ system" can be found in the specification at least at page 5, lines 5-9, where Applicants teach that prior to insertion of the implant into an organ system, the implant has the characteristics of being both rigid and easily shapeable, and at page 11, lines 5-9, where Applicants teach that a plasticizer added to the matrix component produces a flexible material. The amendments presented herein add no new matter.

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

### **II. Claims 1-17 Are Novel and Non-Obvious Over Dunn et al.**

At page 2, paragraph 1 of the instant Office Action, claims 1-9, 11, 13-15, and 17 remain rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO 91/01126. At page 3, paragraph 3 of the instant Office Action, claims 10, 12 and 16 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al.

Applicants respectfully traverse these rejections. As amended, the pending claims are directed to biodegradable implants and methods for making biodegradable implants wherein the implant comprises rigid matrix to which a plasticizer is added such that the implant is **flexible and rigid prior to insertion into an organ system**, and such that the plasticizer substantially exits from the implant after coming into contact with tissue fluids of an organ system. The claimed physical characteristics of rigidity and flexibility prior to implantation are beneficial because they enable one of skill in the art to easily shape the implants into a variety of forms (page 4, lines 12-15). Although the rigidity of the implant increases substantially after insertion into an organ system, the claimed implants have sufficient rigidity prior to insertion to provide structural integrity to the implant. For example, prior to implantation into an organ system, implants of the instant invention have ample rigidity to be shaped into structures such as a fixation plate (page 9, lines 1-22; Figure 4). The flexibility of Applicants' implants enable them to be shaped to fit a tissue structure in a very precise manner such that a good fit may be achieved upon implantation to allow regenerating tissue to grow in the correct shape with no damage to the surrounding tissue (specification, page 2, lines 8-11). Thus, Applicants' claimed implants have a beneficial balance of flexibility and rigidity prior to insertion (specification page 2, lines 7-8).

At page 5 of the instant Office Action, the Examiner states that the instant claims recite that the implant comprises a "rigid matrix component" and that Dunn et al. provides such a component once implanted into the patient. The Examiner asserts that the NMP dissipates out of the matrix and creates pores, which leaves the implant slightly flexible and less rigid.

Without acquiescing to the Examiner's rejections, Applicants respectfully submit that the instant claims have been amended to clarify that the claimed implants are both flexible and rigid prior to insertion into an organ system. Specifically with respect to method claims 9 and 10, the

recited matrix is rigid prior to addition of the plasticizer. Furthermore, Applicants' claimed implants cure after implantation, i.e., when the plasticizer substantially exits from the implant after coming in contact with tissue fluids of an organ system. Dunn et al. neither teaches nor suggests implants that are both flexible and rigid prior to implantation. In addition, Dunn et al. does not teach the method of adding plasticizer to an already rigid matrix to produce the flexible implant. Nor does Dunn et al. teach implants which both cure in an organ system and have the physical characteristics of flexibility and rigidity. Instead, Dunn et al. teaches liquid implants (page 11, lines 2-5) or implants that are cured/set outside the body (page 2, lines 27-29 and page 4, lines 12-14). The latter implants are already cured when they are implanted and thus would not meet the limitation that the plasticizer substantially exits from the implant after coming in contact with tissue fluids of an organ, as required by the instant claims. Thus, one of skill in the art would not arrive at the claimed invention based on the teachings of Dunn et al.

Accordingly, as Dunn et al. fails to teach or suggest Applicants' claimed invention, Applicants request that the rejections of claims 1-9, 11, 13-15 and 17 under 35 U.S.C. §102(b) and claims 10, 12 and 16 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

### III. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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